IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

FILED
JAN 24 2019
U.S. DISTRICT COURT-WVND
WHEELING, WV 26003

JAPAN TOBACCO INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:19-CV-12

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Japan Tobacco Inc. (hereinafter "Plaintiff"), for its Complaint against defendant Mylan Pharmaceuticals Inc. alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Japan Tobacco Inc. ("JT") is a corporation organized and existing under the laws of Japan, having a principal place of business at 2-1, Toranomon 2-Chome, Minato-Ku, Tokyo 105-8422, Japan.

3. On information and belief, defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized and existing under the laws of the State of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, defendant Mylan directly or indirectly develops, manufactures, markets and distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. This Court has jurisdiction over Mylan because, on information and belief, Mylan is a company organized and existing under the laws of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. This Court also has jurisdiction over Mylan, because, *inter alia*, this action arises from acts by Mylan directed toward West Virginia and because Mylan has purposefully availed itself of the rights and benefits of West Virginia law by engaging in systematic and continuous contacts with West Virginia. Mylan regularly and continuously transacts business within the State of West Virginia, including by selling pharmaceutical products in West Virginia, either on its own or through its affiliates. Upon information and belief, Mylan derives substantial revenue from the sale of those products in West Virginia and has availed itself of the privilege of conducting business within the State of West Virginia.

7. This Court also has jurisdiction over Mylan because Mylan has availed itself of the legal protections of the State of West Virginia by, among other things, selecting the State of West Virginia as its place of incorporation and by consenting to jurisdiction and/or asserting counterclaims in prior cases filed in this district under the Hatch-Waxman Act. *See, e.g.*, *Novartis Pharms. Corp. et al. v. Mylan Pharms., Inc. et al.*, No. 1:14-cv-00111-IMK (N.D. W. Va. Dec. 4, 2014); *Teva Pharms. USA, Inc. et al. v. Mylan Pharms., Inc. et al.*, No. 1:14-cv-00167-IMK (N.D. W. Va. Nov. 26, 2014); *Acorda Therapeutics, Inc. et al. v. Mylan Pharms., Inc. et al.*, No. 1:14-cv-00139-IMK (N.D. W. Va. Jan. 12, 2015); *Pfizer Inc. et al. v. Mylan Inc.*

et al., No. 1:15-cv-00004-IMK (N.D. W. Va. Feb. 13, 2015); *Noven Pharms., Inc. et al. v. Mylan Techs., Inc. et al.*, No. 1:15-cv-00069-IMK-MJA (N.D. W. Va. May 4, 2015); *Novartis Pharms. Corp. et al. v. Mylan Pharms. Inc.*, 1:17-cv-000054-IMK (N.D. W. Va. Apr. 10, 2017).

8. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Mylan.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Mylan resides in the Northern District of West Virginia, and/or has committed acts of infringement in the Northern District of West Virginia and has a regular and established place of business in the Northern District of West Virginia.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

10. JT discovered the anti-viral compound called elvitegravir.

11. Elvitegravir is (S)-6-(3-Chloro-2-fluorobenzyl)-1-(1-hydroxymethyl-2-methylpropyl)-7-methoxy-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

12. JT is the owner of U.S. Patent No. 8,633,219 ("'219 patent"), which was duly and legally issued on January 21, 2014. A true copy of the '219 patent is attached as Exhibit A.

13. Claim 1 of the '219 patent claims a method for treating an HIV infectious disease in a human patient comprising administering to a human patient a combination of (a) an effective amount of elvitegravir, (b) an effective amount of the compound tenofovir disoproxil fumarate, and (c) an effective amount of the compound emtricitabine. Claim 2 of the '219 patent claims the method of claim 1, wherein (a), (b) and (c) are formulated together and administered as a single therapeutic composition. Claim 5 of the '219 patent claims a composition for treating an HIV infectious disease in a human patient comprising an effective amount of elvitegravir, an effective amount of tenofovir disoproxil fumarate, and an effective amount of emtricitabine.

14. In an agreement dated March 22, 2005, JT licensed certain patents, technology and know-how concerning elvitegravir to Gilead Sciences, Inc. ("Gilead") for the purpose of having Gilead develop, obtain regulatory approval for, and commercialize elvitegravir-containing drug products.

15. Pursuant to the March 22, 2005 agreement between JT and Gilead, Gilead sought regulatory approval for, and obtained, New Drug Application ("NDA") No. 203100 for Stribild® (elvitegravir 150 mg dosage strength, cobicistat 150 mg dosage strength, emtricitabine 200 mg dosage strength, and tenofovir disoproxil fumarate 300 mg dosage strength) fixed-dose combination tablets.

16. Stribild® was approved by the United States Food and Drug Administration ("FDA") on August 27, 2012. Stribild® currently is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older weighing at least 35 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Stribild®.

17. On information and belief, Mylan submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale and sale of elvitegravir 150 mg dosage strength, cobicistat 150 mg dosage strength, emtricitabine 200 mg dosage strength, and tenofovir disoproxil fumarate 300 mg dosage strength fixed-dose combination tablets ("Mylan's ANDA Product") before the expiration of the '219 patent.

18. Plaintiff received from Gilead a copy of a Mylan notice letter dated December 12, 2018 ("Notice Letter"), disclosing that Mylan had submitted its ANDA to the FDA with a 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification. The Notice Letter alleged, *inter alia*, that claims 1, 2 and 5 of the '219 patent are invalid. However, Mylan in its Notice Letter did not allege that its ANDA Product will not infringe claims 1, 2 and 5 of the '219 patent.

19. This action was commenced within 45 days of the December 12, 2018 date of the Notice Letter.

20. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Mylan's ANDA Product before the expiration of the '219 patent, Mylan committed an act of infringement under 35 U.S.C. § 271(e)(2).

21. On information and belief, when Mylan filed its ANDA, Mylan was aware of the '219 patent and that the filing of its ANDA with a request for its approval prior to the expiration of the '219 patent was an act of infringement of that patent.

22. On information and belief, the commercial manufacture, use, offer for sale, or sale in the United States and/or importation into the United States of Mylan's ANDA Product will infringe claims 1, 2 and 5 of the '219 patent.

23. On information and belief, Mylan's ANDA Product, if approved, will be a composition for treating an HIV infectious disease in a human patient comprising an effective amount of elvitegravir, an effective amount of tenofovir disoproxil fumarate, and an effective amount of emtricitabine. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's ANDA Product will directly infringe claim 5 of the '219 patent.

24. On information and belief, Mylan's ANDA Product, if approved, will contain instructions for practicing a method of treating an HIV infectious disease in a human patient comprising administering to a human patient a combination of (a) an effective amount of elvitegravir, (b) an effective amount of tenofovir disoproxil fumarate, and (c) an effective amount of emtricitabine, wherein (a), (b) and (c) are formulated together and administered as a single therapeutic composition. On information and belief, if Mylan's ANDA Product is approved, the practice of such instructions will result in the direct infringement of claims 1 and 2 of the '219 patent. On information and belief, if Mylan's ANDA Product is approved, Mylan will actively induce, encourage, and abet this direct infringement with knowledge of the '219 patent, and that its acts will induce infringement of claims 1 and 2 of the '219 patent.

25. On information and belief, if Mylan's ANDA Product is approved, Mylan will commercially manufacture, offer for sale and/or sell that product, which will be specifically labeled for use in a method for treating an HIV infectious disease in a human patient comprising administering to a human patient a combination of (a) an effective amount of elvitegravir, (b) an effective amount of tenofovir disoproxil fumarate, and (c) an effective amount of emtricitabine, wherein (a), (b) and (c) are formulated together and administered as a single therapeutic composition. On information and belief, if Mylan's ANDA Product is approved, Mylan's ANDA Product will constitute a material part of a method for treating an HIV infectious disease in a human patient comprising administering to a human patient a combination of (a) an effective amount of elvitegravir, (b) an effective amount of tenofovir disoproxil fumarate, and (c) an effective amount of emtricitabine, wherein (a), (b) and (c) are formulated together and administered as a single therapeutic composition. On information and belief, if Mylan's ANDA Product is approved, Mylan will contributorily infringe claims 1 and 2 of the '219 patent, and

will do so with knowledge of the '219 patent, and that its ANDA Product is especially made or especially adapted for use in infringing claims 1 and 2 of the '219 patent and is not suitable for a substantial noninfringing use.

26. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the ANDA relating to Mylan's ANDA Product be a date that is no earlier than the April 24, 2030 expiration of the '219 patent, and an award of damages for any commercial sale or use of Mylan's ANDA Product and any act committed by Mylan with respect to the subject matter claimed in the '219 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

27. On information and belief, Mylan has taken and continues to take active steps toward the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product, including seeking approval of its ANDA Product under Mylan's ANDA.

28. There is a substantial and immediate controversy between Plaintiff and Mylan concerning the '219 patent. Plaintiff is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Mylan will directly infringe, induce infringement of and/or contributorily infringe claims 1, 2 and 5 of the '219 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. Judgment that Mylan has directly infringed, induced infringement of and/or contributorily infringed claims 1, 2 and 5 of the '219 patent by filing an ANDA relating to Mylan's ANDA Product;

B. A permanent injunction restraining and enjoining Mylan and its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from engaging in the

commercial manufacture, use, offer to sell, or sale in the United States, and/or importation into the United States, of Mylan's ANDA Product, as claimed in claims 1, 2 and 5 of the '219 patent;

C. An order that the effective date of any approval of the ANDA relating to Mylan's ANDA Product be a date that is not earlier than the expiration of the right of exclusivity under the '219 patent;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product will directly infringe, induce infringement of and/or contributorily infringe claims 1, 2 and 5 of the '219 patent;

E. Damages from Mylan for the infringement, inducement of infringement and/or contributory infringement of the '219 patent;

F. The costs and reasonable attorney fees of Plaintiff in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: January 24, 2019

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